



DEPARTMENT OF HEALTH AND HUMAN SERVICE

Public Health Service

Food and Drug Administration
New Orleans District
Southeast Region
6600 Plaza Drive, Suite 400
New Orleans, LA 70127

Telephone: 504-253-4500
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March 22, 2000

WARNING LETTER NO. 2000-NOL-17

FEDERAL EXPRESS
OVERNIGHT DELIVERY

Mr. Roy J. Robin, Owner
Bayou Land Seafood
1008 Vincent Berard Road
Breaux Bridge, Louisiana 70517-7114

Dear Mr. Robin:

On May 19 - 21, 1999, a U.S. Food and Drug Administration (FDA) investigator conducted an inspection of your crawfish processing facility, located at 1008 Vincent Berard Road, Breaux Bridge, Louisiana. The inspection was conducted to determine compliance with FDA's seafood processing regulations, Title 21, *Code of Federal Regulations* (CFR), Part 123 and the Current Good Manufacturing Practice (CGMP) regulations for foods CFR, Part 110. Our investigator documented numerous deviations from these regulations. This causes your crawfish products to be adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act.

The seafood processing regulations, which became effective on December 18, 1997, require that you implement a preventive system of food safety controls known as Hazard Analysis Critical Control Point (HACCP). HACCP essentially involves: (1) identifying food safety hazards that, in the absence of controls, are reasonably likely to occur in your products; and (2) having controls at "critical control points" in the processing operation to eliminate or minimize the likelihood that the identified hazards will occur. These are the kinds of measures that prudent processors already take. HACCP provides a systematic way of taking those measures that demonstrates to us, to your customers, and to consumers, that you are routinely practicing food safety by design. Seafood processors that have fully operating HACCP systems advise us that they benefit from it in several ways, including having a more safety oriented workforce, having less product waste, and having fewer problems generally.

During the May 1999 inspection, the FDA investigator observed shortcomings in your system that were similar to those pointed out in the March 16 and 17, 1998, inspection and stated in the untitled letter sent to your firm on May 18, 1998. We acknowledged receipt of your revised HACCP plan during the May 19-21, 1999 inspection. However, it was not fully implemented during our inspection. This HACCP plan is deficient in the following areas:

- You must have a HACCP plan that lists the critical limits that must be met, to comply with 21 CFR 123.6(c)(3). However, your firm's HACCP plan for crawfish tail meat lists a critical limit

- You must have a HACCP plan that lists the critical limits that must be met, to comply with 21 CFR 123.6(c)(3). However, your firm's HACCP plan for crawfish tail meat lists a critical limit (TBA) at the cooking, cooling and ice slush critical control points that is not adequate to control pathogen growth and toxin formation. The designation TBA needs to be defined. In addition, your firm's HACCP plan for crawfish tail meat lists time and temperature based critical limits at the cooling, hand peeling, weight/package critical control points that are not adequate to control pathogen growth and toxin formation;
- Since you chose to include corrective actions in your HACCP plan, your described corrective actions must be appropriate to comply with 21 CFR 123.7(b). However, your corrective action plan for crawfish tail meat at the cooling, hand peeling, weight/package, ice slush and ice pack storage critical control points to control pathogen growth and toxin formation is not appropriate. You listed corrective actions that do not include correcting the cause of the deviation (e.g. the corrective action listed at the hand peeling critical control point focuses on the product time and temperature exposure, but it fails to state how to resolve the cause of the deviation);
- You must have a HACCP plan that lists monitoring procedures for each critical control point to comply with 21 CFR 123.6(c)(4). However, your firm's HACCP plan for crawfish tail meat does not list a monitoring procedure for the temperature of the product at the hand peeling critical control point to control pathogen growth and toxin production;

During the May 19-21, 1999 inspection, the FDA investigator also provided your firm with a copy of the Domestic Seafood HACCP Report (Form FDA 3501) and the Form FDA 483, which presents his evaluation of your firm's performance regarding various aspects of the HACCP and CGMP requirements. The Form FDA 483 is enclosed for your review. The observations of concern to us are as the follows:

- Failure to implement the monitoring procedures listed in your HACCP plan as required by 21 CFR, Part 123.6(b). In addition, your firm did not follow the temperature monitoring procedures at the cooling and refrigerated storage critical control points to control pathogen growth and toxin formation in your HACCP plan for crawfish tail meat.
- Failure to have and implement a HACCP plan, to control food safety hazards or sanitation records associated with the production of various prepared food products such as seafood gumbo, shrimp, crab, or crawfish etouffee as required by 21 CFR, Part 123.6(b);
- Failure to adequately address the control of *Clostridium botulinum* growth/toxin formation in the HACCP plan for frozen, vacuum-packaged peeled crawfish tail meat as required by 21 CFR Part 123.6(b). The label for your vacuum-packaged cooked crawfish tail meat provides two storage condition declarations. The label declaration "**** PEELED CRAWFISH TAILS *** PERISHABLE *** KEEP UNDER REFRIGERATION *** WHEN FROZEN *** DO NOT REFREEZE ****" is misleading. The label can be interpreted to mean that refrigerated or frozen storage is acceptable during distribution of the crawfish to the final consumer. This is a concern because FDA considers refrigerated, vacuum-packaged seafood to be a potential health risk, especially products that can be considered ready-to-eat. Frozen distribution is an acceptable storage condition for vacuum-packaged crawfish if the crawfish meat is immediately frozen after processing, kept frozen throughout distribution, and labeled to be held frozen and to be thawed under refrigeration immediately before use (e.g., "important, keep frozen until used, thaw under refrigeration"). Under these conditions the formation of *Clostridium botulinum* toxin may not be

a significant hazard during storage and distribution and, therefore, HACCP controls for these steps may not be required;

- Failure to implement adequate sanitation monitoring in that the Sanitation Standard Operating Procedure (SSOP) daily checklist records dated May 19-20, 1999, do not reflect the conditions observed, as required by 21 CFR, Part 123.11(b). The conditions observed are specifically:

1. On May 19, 1999, two live flies in the cook room directly contacted cooked crawfish, the cooked crawfish baskets, and the cooked crawfish holding chute;
2. On May 19, 1999, two live flies were in the peeling room and directly contacted cooked crawfish on the peeling table;
3. On May 19, 1999, approximately 25 live flies were observed in the dock/loading area just outside of the cook room door;
4. On May 20, 1999, five live flies in the cook room directly contacted cooked crawfish and cooking baskets;
5. On May 20, 1999, two peeling employees and one packing employee routinely handled wet cloths at their station and routinely resumed handling peeled tail meat without washing and sanitizing their hands;
6. On May 20, 1999, two peeling employees did not wash and sanitize their hands after returning from a break and prior to peeling crawfish tail meat; and,
7. On May 20, 1999, one peeling employee wore a ring and one peeling employee wore a cloth bracelet while peeling crawfish tail meat; the ring and the cloth bracelet continuously contacted cooked crawfish and peeled crawfish tail meat.

Objectionable equipment and insanitary conditions as listed on Form FDA 483 and Form FDA 3501 are an indication that sanitation monitoring [21 CFR, Part 123.11(b)] at the firm is inadequate. Calling your attention to the objectionable insanitary conditions in this letter is in the interest of having your firm improve its sanitation program consistent with the HACCP principles. A failure to make appropriate corrections and practices could cause your HACCP processing system to be found unacceptable during a future FDA inspection. The noted objectionable insanitary conditions include the following:

- Two perforated cooking baskets containing cooked crawfish were splashed four times with murky, warm water containing crawfish liquors and debris that had accumulated during previous cooling operations;
- The outer lip of the cooked crawfish transport container directly contacted the wet, dirty, peeling room floor where there is heavy foot traffic and crawfish debris. The lip area then directly contacted cooked crawfish and the peeling tables. The transport container contacted cooked crawfish and food contact surfaces after contacting the wet, dirty floor on four different occasions on May 19, 1999, and on two different occasions on May 20, 1999;


- On one occasion, the lip area of the cooked crawfish transport container directly contacted the same area of the chute tray where a peeling employee had previously stepped. The same area of the transport container then directly contacted the cooked crawfish and peeling table;
- The stainless steel cooked crawfish holding chute was abraded and had rough seam welds. Brownish residues were observed in the abrasions and seam welds;
- After cooking baskets containing cooked crawfish were placed in the warm water of the chill tank which contained crawfish liquors and debris, up to three cooking baskets at the same time were routinely placed on holding racks in the cooking room because the cooked crawfish chute was full. The cooked crawfish routinely remained in the cook room for a minimum of one and one-half hours prior to peeling and packing operations. Throughout operation on May 19, 1999 and May 20, 1999, the total time from contact of the cooked crawfish to the storage of packaged crawfish tail meat ranged from no less than two hours and forty-five minutes to more than four hours.

The above identification of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure adherence with each requirement of the applicable regulations. You should take prompt action to correct these deviations. Failure to promptly correct the deviations may result in regulatory action without further notice. These include seizure and/or injunction.

We are aware that at the close of the inspection you made a verbal commitment to correct the observed deficiencies. Our investigator documented this commitment by annotation of the FDA Form 483. You should notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which corrections will be completed.

Your reply, relating to these concerns, should be addressed to the U.S. Food and Drug Administration, Attention: Dawn P. Hall, Compliance Officer, 6600 Plaza Drive, Suite 400, New Orleans, Louisiana. If you have any questions regarding the implementation of the HACCP regulations, you may contact Ms. Hall at (504) 253-4519.

Sincerely,



Lawrence A. D'Hoostelaere, Ph.D.
Acting District Director
New Orleans District

Enclosure: FDA-483